



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,482	01/02/2002	Irun R. Cohen	COHEN=42A	5950
28765	7590	10/31/2005	EXAMINER	
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006			AEDER, SEAN E	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 10/31/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/032,482	Applicant(s) COHEN ET AL.	
	Examiner Sean E. Aeder, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-12 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12 and 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The Amendments and Remarks filed on 10/13/05 in response to the Office Action of 7/6/05 are acknowledged and have been entered.

Claims 8-12 and 17-28 were pending.

Claims 8, 10, 18-19, 23-24, and 27-29 have been amended by Applicant.

Claims 8-12 and 17-28 are currently under examination.

The text of those sections of Title 35 U.S.C. code not included in this Office Action can be found in a prior Office Action.

Objections

Applicant, in addressing the objection to the specification for inconsistencies, has amended claims 18 and 23 to recite "mAb 240, mAb 246, and mAb 241". Thus, the objection is withdrawn.

Rejections Withdrawn

The rejection of claims 19 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicant regards as the invention is withdrawn in view of amendments.

The rejection of claims 8-9, 17, 20, and 27-28 under 35 U.S.C. 103(a) as being unpatentable over Zusman et al (The Cancer Journal 10:116-120, 1997) and further in view of Carson et al (US Patent 5,068,177) is withdrawn in view of arguments.

Response to Arguments

The response filed on 10/13/05 to the rejection of claims 8-12 and 17-28 under 35 U.S.C., first paragraph, as failing to comply with the written description requirement has been carefully considered but is deemed not to be persuasive.

With the response, claim 8 was amended to recite that the claimed synthetic peptide "is 7 to 30 amino acid residues in length of a variable region of an anti-p53 mAb and contains a sequence of a CDR of the heavy or light chain of the ~~[[an]]~~ anti-p53 mAb, and salts ~~and chemical derivatives thereof~~". The amendment thus clarifies that the claimed synthetic peptide contains fragments of CDR sequences and optional flanking amino acids from *an* anti-p53 mAb. The response suggests that the specification provides sufficient disclosure such that one skilled in the art would reasonably conclude that Applicants had possession of the claimed invention at the time the application was filed. Specifically, the response points to the Examples, which demonstrate preparation of CDR-based peptides of anti-p53 mAbs and their use for inducing anti-p53 immunity.

In response to this argument, the claims are still drawn to every synthetic peptide 7 to 30 amino acid residues in length of a variable region of any and every anti-p53 mAb

Art Unit: 1642

that contains a sequence of a CDR of the heavy or light chain of said anti-p53 mAb.

The only CDR sequences disclosed in the specification are in the context of peptides from mAb 240, mAb 246, and mAb 421. There is no disclosure of any CDR sequences that is not in this context as broadly encompassed in the claims. Thus, one of skill in the art would not ^{recognize} understand that Applicant had possession of the claimed invention at the time the instant application was filed.

Therefore, in view of the lack of guidance in the specification one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention. However, this rejection could be obviated by restricting the claimed invention to a synthetic peptide capable of eliciting antibodies to p53, which peptide is 7 to 30 amino acids in length of a variable region of mAb240, mAb246, or mAb241, and contains a sequence of a CDR of the heavy or light chain of mAb240, mAb246, or mAb241, and salts thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

A handwritten signature in black ink, appearing to read "Gary B. Nickol". The signature is written in a cursive, flowing style.

**GARY B. NICKOL, PH.D.
PRIMARY EXAMINER**